

Claims

1. A process for preparing the rosiglitazone maleate polymorph (Compound 1) substantially free of any other polymorphic forms, which comprises crystallising
5 rosiglitazone maleate in a solvent or mixture of solvents with a dielectric constant such that it provides Compound 1 substantially free of any other polymorphic forms.
2. A process for preparing the rosiglitazone maleate polymorph, Compound 1 substantially free of other polymorphs, which comprises crystallising rosiglitazone maleate in a solvent with a dielectric constant of less than 21 or a mixture of
10 solvents wherein at least one solvent has a dielectric constant of less than 21.
3. A process as claimed in claim 1 or claim 2 wherein the solvent is selected from anisole, isopropyl acetate, ethyl acetate, dichloroethane, methyl isobutyl ketone, n-butanol, propan-2-ol, toluene, dimethylcarbonate, or tetrahydrofuran or mixtures thereof.
- 15 4. A process as claimed in any of claims 1 to 3 wherein the crystallisation solvent is a mixture selected from a ethyl acetate and IMS, toluene and IMS or dimethylcarbonate and IMS.
5. A process for preparing the rosiglitazone maleate polymorph (Compound 1) essentially free of any other polymorphic forms, which comprises crystallising
20 rosiglitazone maleate in a solvent or mixture of solvents with a dielectric constant such that it provides Compound 1 essentially free of any other polymorphic forms.
6. A process for preparing the Compound 1 essentially free of any other polymorphic forms of rosiglitazone maleate which comprises crystallising rosiglitazone maleate from a solvent or mixture of solvents wherein the solvent or at
25 least one of the solvents has a dielectric constant of less than 14.
7. A process as claimed in claim 6 for preparing the Compound 1 essentially free of any other polymorphic forms of rosiglitazone maleate which comprises crystallising rosiglitazone maleate from a solvent or mixture of solvents with a dielectric constant of less than 14.
- 30 8. A process as claimed in claim 6 or claim 7 wherein the solvent has a dielectric constant of greater than 2.8 and less than 14.
9. A process as claimed in any of claims 5 to 8 wherein the solvent is tetrahydrofuran.
10. A process for preparing Compound 1 which comprises seeding a solution of
35 rosiglitazone maleate in a suitable solvent with a dielectric constant > 21, with

Compound 1 essentially free of other polymorphic forms prepared according to the process as claimed in any of claims 5 to 9.

11. A process as claimed in claim 10 wherein the solvent is denatured ethanol.

12. The use of Compound 1 essentially free of other polymorphs, prepared by
5 the process of any of claims 5 to 9 as a seed material in a crystallisation process for preparing Compound 1 essentially free of other polymorphs of rosiglitazone maleate.

13. A process for preparing the Compound 1 essentially free of any other
polymorphic forms of rosiglitazone maleate which comprises crystallising
10 rosiglitazone maleate from a solvent or mixture of solvents selected from anisole, isopropyl acetate, ethyl acetate, dichloroethane, dimethyl carbonate, methyl isobutyl ketone, tetrahydrofuran or a mixture ethyl acetate and denatured ethanol(IMS).

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